



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.        | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|-------------|----------------------|---------------------|------------------|
| 10/815,198             | 03/25/2004  | William A. Palmisano | 41543 US 0103       | 8645             |
| 5179                   | 7590        | 08/28/2007           | EXAMINER            |                  |
| PEACOCK MYERS, P.C.    |             |                      | HARRIS, ALANA M     |                  |
| 201 THIRD STREET, N.W. |             |                      | ART UNIT            |                  |
| SUITE 1340             |             |                      | PAPER NUMBER        |                  |
| ALBUQUERQUE, NM 87102  |             |                      | 1643                |                  |
| MAIL DATE              |             | DELIVERY MODE        |                     |                  |
| 08/28/2007             |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                  |
|------------------------------|------------------------|------------------|
| <b>Office Action Summary</b> | Application No.        | Applicant(s)     |
|                              | 10/815,198             | PALMISANO ET AL. |
|                              | Examiner               | Art Unit         |
|                              | Alana M. Harris, Ph.D. | 1643             |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02/12/07; 06/04/07.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 3,7 and 10-13 is/are pending in the application.  
 4a) Of the above claim(s) 7,12 and 13 is/are withdrawn from consideration.  
 5) Claim(s) 10 is/are allowed.  
 6) Claim(s) 3 and 11 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 03/25/04; 07/19/04; 01/03/06.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group II (claims 3 and 4) in the reply filed on June 4, 2007 is acknowledged. The traversal is on the ground(s) that the preliminary amendment of February 12, 2007 and its corresponding claims would not be an undue burden to the Examiner to review claims 3 and 7 in a single search, see page 8 of Remarks, 3<sup>rd</sup> paragraph. Applicants also note MPEP section 804.04, which cites up to ten sequences can be examined. This is not found persuasive because while the PAX family is collectively art known to be transcription factors the genes differs in nucleic acid sequences. Moreover, it is within the Examiner's discretion to determine the number of sequences that will be searched and the amount of burden.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3, 7 and 10-13 are pending.

Claims 1, 2, 4-6, 8 and 9 have been cancelled.

Claims 3 and 7 have been amended.

Claims 10-13 have been added.

Claims 3, 10 and 11 are examined on the merits.

***Specification***

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 16, line 2. Applicant is required to

delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicants should review the entire specification for similar errors.

***Claim Objections***

4. Claim 11 is objected to because of the following informality: it recites "hiological" and should cite "histological". Correction is required.

***Sequence Compliance***

5. This application contains sequence disclosures within claim 10 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicants are requested to amend it to include the sequence identifiers ensuring that these added SEQ ID numbers are not new matter.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 11 recites the limitation "the [histological] sample", however there is insufficient antecedent basis for this limitation in claim 3.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 3 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2005/0069924 A1 (effective filing date February 23, 2001). The publication discloses a method for detecting a cellular proliferative disorder in a sample from a patient (i.e. plasma, serum, stool, ejaculate, sputum, saliva, cerebrospinal fluid, or blood or a sample embedded in paraffin, tissues, or animal cell membranes of the sample), see abstract and page 8, section 0065.

The disclosed invention provides invention[s] include determining, in a nucleic acid-containing specimen taken from a subject, the methylation state of a gene or regulatory sequences associated therewith [(i.e. promoter region)], wherein the methylated regions of the gene and associated regulatory sequences are contained within CpG islands (i.e., CpG rich regions). In the instant case, identification of differentially methylated sequences and CpG islands were recognized in the 5' region of the human B-cell specific transcriptional factor gene PAX5 utilizing bisulfite modification and methylation-specific PCR (MSP). Aberrant methylation typically includes hypermethylation as compared with the same regions of the gene or regulatory

Art Unit: 1643

sequences in a subject not having the cellular proliferative disorder, see page 3, section 0017; page 5, section 0034; page 13, sections 0099; and page 14, sections 0104- 0106.

Absent evidence to the contrary the disclosed PAX5 reads on PAX5  $\beta$ .

The method of monitoring cancer in the biological specimen included a PCR reaction and amplification methylated templates under a higher annealing temperature, see page 12, section 0097; page 13, section 0099; and page 14, sections 0104 and 0105.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

-WO 99/63110 "Diagnosis and Treatment of Cancer" (published December 9, 1999) and corresponding database sheets.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.  
PRIMARY EXAMINER  
  
Alana M. Harris, Ph.D.  
20 August 2007